

Industry Survey of SPL Business Process

1. In order to accurately combine multiple surveys coming from your corporation, we would like to know your corporate name. Your corporate name is not used for any other purpose and will not be made public. Corporate Name:		
		Response Count
		5
	answered question	5
	skipped question	1

2. You may not be familiar with the electronic SPL submission plans at the corporate level. If you are answering this survey for a particular business group, we need to collate the various group responses for your corporation. I am responding for:			
		Response Percent	Response Count
My entire corporation (e.g., your organization has three business units that handle medicinal products and you are answering for all of them)	<div><div></div></div>	66.7%	4
Only a group (e.g., your organization has multiple units/divisions covering Human Pharmaceutical, Human Biologic/Vaccine, Animal Health and Over-the-Counter/Consumer HealthCare and you are answering for only one or a few groups)	<div><div></div></div>	33.3%	2
Group/Unit Name(s):			3
answered question			6
skipped question			0

3. We will be periodically tabulating the results from this survey. You can fill the survey out more than once between now and the FDA’s implementation date for eListing (currently targeted for June 1, 2009) Is this the first time you are filling out this survey?

		Response Percent	Response Count
First time	<div></div>	83.3%	5
Second/Multiple entry	<div></div>	16.7%	1
	answered question		6
	skipped question		0

4. If you are not familiar with your company’s NDC Labeler Codes and how they are maintained, please choose SKIP and click on NEXT which will skip you to the Establishment Registration section.

		Response Percent	Response Count
Continue	<div></div>	83.3%	5
SKIP	<div></div>	16.7%	1
	answered question		6
	skipped question		0

5. How many active NDC Labeler Codes does your corporation/business unit have?		
		Response Count
		5
	<i>answered question</i>	5
	<i>skipped question</i>	1

6. How do you currently store your NDC Labeler Code submission <u>documents</u> (Form 2656)?			
		Response Percent	Response Count
Electronic (e.g., MS Word, PDF)	<div><div></div></div>	20.0%	1
Paper	<div><div></div></div>	80.0%	4
Other/I don't know, please provide details		0.0%	0
	<i>answered question</i>		5
	<i>skipped question</i>		1

7. How do you currently store your NDC Labeler Code <u>data</u> ?			
		Response Percent	Response Count
One or more database or document management system(s) (e.g. ORACLE or SQLServer database, SAP resource management system, Documentum docbase)		0.0%	0
Other electronic format (e.g., spreadsheet, Word or text document)	<div></div>	40.0%	2
Paper	<div></div>	60.0%	3
Other, please provide details:		0.0%	0
	answered question		5
	skipped question		1

8. Who currently submits Labeler Code Requests?			
		Response Percent	Response Count
Regulatory Product Listing person	<div></div>	80.0%	4
Regulatory Product Labeling person		0.0%	0
Other/I don't know, please provide details:	<div></div>	20.0%	1
	answered question		5
	skipped question		1

9. In the future, who will submit electronic Labeler Code Requests in SPL?			
		Response Percent	Response Count
Regulatory Product Listing person	<div><div></div></div>	80.0%	4
Regulatory Product Labeling person		0.0%	0
Other/I don't know, please provide details:	<div><div></div></div>	20.0%	1
	answered question		5
	skipped question		1

10. Do you know what a D-U-N-S Number is?			
		Response Percent	Response Count
Yes	<div><div></div></div>	100.0%	5
No		0.0%	0
	answered question		5
	skipped question		1

11. Do you know the D-U-N-S Number for each Labeler site?			
		Response Percent	Response Count
Yes, all sites	<div><div></div></div>	80.0%	4
Yes, >75% of sites		0.0%	0
Yes, approx 50% of sites	<div><div></div></div>	20.0%	1
Yes, <25% of sites		0.0%	0
No, none		0.0%	0
	answered question		5
	skipped question		1

12. Do you need to request any D-U-N-S numbers?			
		Response Percent	Response Count
Yes, all sites		0.0%	0
Yes, >75% of sites		0.0%	0
Yes, approx 50% of sites	<div><div></div></div>	25.0%	1
Yes, <25% of sites	<div><div></div></div>	25.0%	1
No, none	<div><div></div></div>	50.0%	2
	answered question		4
	skipped question		2

13. How do you plan to identify (or how did you identify) your Labeler D-U-N-S Number(s)?			
		Response Percent	Response Count
Check with internal corporate financial personnel	<div><div></div></div>	60.0%	3
Go directly to the Dun and Bradstreet website	<div><div></div></div>	40.0%	2
Use a third party source for assistance		0.0%	0
No plans yet		0.0%	0
Other, please provide details	<div><div></div></div>	20.0%	1
	answered question		5
	skipped question		1

14. If you are not familiar with your company’s Establishment Registrations (Form 2656) and how they are maintained, please skip to the Product Listing section.			
		Response Percent	Response Count
SKIP		0.0%	0
Continue	<div><div></div></div>	100.0%	5
	answered question		5
	skipped question		1

15. How many active Establishment sites does your corporation/business unit have?				
		Response Average	Response Total	Response Count
Number of U.S. Establishments		2.75	11	4
Number of Foreign Establishments		5.00	20	4
	answered question			4
	skipped question			2

16. Are your Establishment Registrations currently sent from one or many location(s)?			
		Response Percent	Response Count
Submissions are made by individuals at each site	<div><div></div></div>	16.7%	1
Submissions are made by a single person/group on behalf of many sites	<div><div></div></div>	83.3%	5
Other, please provide details:		0.0%	0
	answered question		6
	skipped question		0

17. How do you currently store your Establishment Registration submission documents (Form 2656)?			
		Response Percent	Response Count
Electronic (e.g., MS Word, PDF)	<div><div></div></div>	33.3%	2
Paper	<div><div></div></div>	66.7%	4
Other/I don't know, please provide details:		0.0%	0
		answered question	6
		skipped question	0

18. How do you currently store your Establishment Registration submission data?			
		Response Percent	Response Count
One or more database or document management system(s) (e.g. ORACLE or SQLServer database, SAP resource management system, Documentum docbase)	<div><div></div></div>	16.7%	1
Other electronic format (e.g., spreadsheet, text document)	<div><div></div></div>	16.7%	1
Paper	<div><div></div></div>	66.7%	4
Other, please provide details:		0.0%	0
		answered question	6
		skipped question	0

19. Who currently submits Establishment Registrations for your corporate/business unit?			
		Response Percent	Response Count
Establishment Registration and/or Product Listing person within a Regulatory Affairs group/department	<div> <div></div> </div>	80.0%	4
Product Labeling person within a Regulatory Affairs group/department		0.0%	0
Establishment Registration and/or Product Listing person within a Manufacturing group/department		0.0%	0
Other, please provide details:	<div> <div></div> </div>	20.0%	1
	answered question		5
	skipped question		1

20. Who (in the future) will submit electronic Establishment Registrations in SPL?			
		Response Percent	Response Count
Establishment Registration and/or Product Listing person within a Regulatory Affairs group/department	<div> <div></div> </div>	100.0%	5
Product Labeling person within a Regulatory Affairs group/department		0.0%	0
Establishment Registration and/or Product Listing person within a Manufacturing group/department		0.0%	0
Other, please provide details:		0.0%	0
	answered question		5
	skipped question		1

21. Have you identified your Registrant site and all your Establishment sites?		
		<div>Response Percent</div> <div>Response Count</div>
Yes, all sites	<div><div></div></div>	<div>80.0%</div> <div>4</div>
Yes, >75% of sites	<div><div></div></div>	<div>20.0%</div> <div>1</div>
Yes, approx 50% of sites		<div>0.0%</div> <div>0</div>
Yes, <25% of sites		<div>0.0%</div> <div>0</div>
No, none		<div>0.0%</div> <div>0</div>
	answered question	
	skipped question	

22. If you have foreign Establishment sites, have you identified your U.S. Agent and Importer(s) for each site?		
		<div>Response Percent</div> <div>Response Count</div>
No Foreign Sites		<div>0.0%</div> <div>0</div>
Yes	<div><div></div></div>	<div>75.0%</div> <div>3</div>
No	<div><div></div></div>	<div>25.0%</div> <div>1</div>
	answered question	
	skipped question	

23. Do you know your D-U-N-S Number(s) assigned to each Registrant and Establishment site?			
		Response Percent	Response Count
Yes, all sites	<div><div></div></div>	40.0%	2
Yes, >75% of sites		0.0%	0
Yes, approx 50% of sites	<div><div></div></div>	40.0%	2
Yes, <25% of sites	<div><div></div></div>	20.0%	1
No, none		0.0%	0
	answered question		5
	skipped question		1

24. How do you plan to identify (or how did you identify) your Registrant and Establishment site D U N S Number(s)?			
		Response Percent	Response Count
Check with internal corporate financial personnel	<div><div></div></div>	60.0%	3
Go directly to the Dun and Bradstreet website	<div><div></div></div>	20.0%	1
Use a third party source for assistance		0.0%	0
No plans yet	<div><div></div></div>	20.0%	1
Other, please provide details	<div><div></div></div>	40.0%	2
	answered question		5
	skipped question		1

25. If you are not familiar with your company's Product Listings (Form 2657, 2658) and how they are maintained, please skip to the FDA eDRL Pilot Program section.			
		Response Percent	Response Count
SKIP	<div></div>	20.0%	1
Continue	<div></div>	80.0%	4
answered question			5
skipped question			1

26. Number of Products by Type: Count only active NDC Product Codes. The Product Code includes the first and second segment of the full NDC code, e.g., 1234-1234-12. > > Center--Product Type							
Approx number of products							
	< 10	11-20	21-50	51-100	101-200	> 200	Response Count
CDER - Prescription	0.0% (0)	0.0% (0)	0.0% (0)	25.0% (1)	50.0% (2)	25.0% (1)	4
CDER - OTC (Over-the-Counter)	66.7% (2)	0.0% (0)	0.0% (0)	0.0% (0)	33.3% (1)	0.0% (0)	3
CDER - API (Active Phamaceutical Ingredient)	0.0% (0)	0.0% (0)	50.0% (1)	0.0% (0)	50.0% (1)	0.0% (0)	2
CDER - Biologic	100.0% (1)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	1
CBER - Biologic including Vaccines	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0
CVM - Prescription	0.0% (0)	100.0% (1)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	1
CVM - VFD (Veterinary Feed Directive)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0
CVM - OTC	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0

Brand/Generic				
	Branded	Generic	Both	Response Count
CDER - Prescription	25.0% (1)	75.0% (3)	0.0% (0)	4
CDER - OTC (Over-the-Counter)	33.3% (1)	66.7% (2)	0.0% (0)	3
CDER - API (Active Phamaceutical Ingredient)	0.0% (0)	0.0% (0)	100.0% (1)	1
CDER - Biologic	0.0% (0)	0.0% (0)	0.0% (0)	0
CBER - Biologic including Vaccines	0.0% (0)	0.0% (0)	0.0% (0)	0
CVM - Prescription	0.0% (0)	0.0% (0)	100.0% (1)	1
CVM - VFD (Veterinary Feed Directive)	0.0% (0)	0.0% (0)	0.0% (0)	0
CVM - OTC	0.0% (0)	0.0% (0)	0.0% (0)	0
	answered question			4
	skipped question			2

27. How do you currently store your Product Listing submission documents?			
		Response Percent	Response Count
Electronic (e.g., MS Word, PDF)	<div><div></div></div>	25.0%	1
Paper	<div><div></div></div>	75.0%	3
Other/I don't know, please provide details:		0.0%	0
		answered question	4
		skipped question	2

28. How do you currently store your Product Listing data?			
		Response Percent	Response Count
One or more database or document management system(s) (e.g. ORACLE or SQLServer database, SAP resource management system, Documentum docbase)		0.0%	0
Other electronic format (e.g., spreadsheet, text document)	<div><div></div></div>	25.0%	1
Paper	<div><div></div></div>	75.0%	3
Other, please provide details:		0.0%	0
		answered question	4
		skipped question	2

29. Who currently submits Product Listings for your corporate/business unit?			
		Response Percent	Response Count
Establishment Registration and/or Product Listing person within a Regulatory Affairs group/department	<div> <div></div> </div>	75.0%	3
Product Labeling person within a Regulatory Affairs group/department		0.0%	0
Establishment Registration and/or Product Listing person within a Manufacturing group/department		0.0%	0
Other, please provide details:	<div> <div></div> </div>	25.0%	1
	answered question		4
	skipped question		2

30. Who (in the future) will submit electronic Product Listing(s) in SPL?			
		Response Percent	Response Count
Establishment Registration and/or Product Listing person within a Regulatory Affairs group/department	<div> <div></div> </div>	75.0%	3
Product Labeling person within a Regulatory Affairs group/department		0.0%	0
Establishment Registration and/or Product Listing person within a Manufacturing group/department		0.0%	0
Other, please provide details:	<div> <div></div> </div>	25.0%	1
	answered question		4
	skipped question		2

31. Have you identified the Labeler, Registrant (if necessary) and the Establishment site(s) for each product?			
		Response Percent	Response Count
Yes, all sites	<div><div></div></div>	50.0%	2
Yes, > 75% of sites		0.0%	0
Yes, approx 50% of sites		0.0%	0
Yes, < 25% of sites	<div><div></div></div>	50.0%	2
No, none		0.0%	0
	answered question		4
	skipped question		2

32. If you are not familiar with the FDA’s electronic Drug Registration and Listing (eDRL) Pilot Program, please skip to the FDA Electronic Submission Gateway (ESG) section.			
		Response Percent	Response Count
SKIP		0.0%	0
Continue	<div><div></div></div>	100.0%	4
	answered question		4
	skipped question		2

33. How did you hear about the FDA eDRL Pilot Program (choose as many as needed)?			
		Response Percent	Response Count
Federal Register Notice	<div><div></div></div>	60.0%	3
Reading the Draft Guidance	<div><div></div></div>	80.0%	4
Communication from Colleague inside your organization		0.0%	0
Communication from Colleague outside your organization	<div><div></div></div>	20.0%	1
Educational/training session provided by FDA	<div><div></div></div>	60.0%	3
Educational/training session provided by group other than FDA		0.0%	0
SPL Working Group WIKI	<div><div></div></div>	60.0%	3
Other, please provide details:	<div><div></div></div>	20.0%	1
	answered question		5
	skipped question		1

34. Do you plan to participate in the FDA eDRL Pilot Program?			
		Response Percent	Response Count
Yes	<div><div></div></div>	80.0%	4
No	<div><div></div></div>	20.0%	1
		<i>answered question</i>	5
		<i>skipped question</i>	1

35. If yes, please complete the following questions			
		Response Percent	Response Count
Expected date of first Labeler Code Request SPL submission	<div><div></div></div>	100.0%	2
Expected date of first Establishment Registration SPL submission	<div><div></div></div>	100.0%	2
Expected date of first Product Listing/Content of Labeling SPL submission	<div><div></div></div>	100.0%	2
		<i>answered question</i>	2
		<i>skipped question</i>	4

36. If you are not planning to participate in the FDA eDRL Pilot Program, please indicate why?			
		Response Percent	Response Count
Won't have software tool(s) or outsourced solution in place before June 1, 2009	<div></div>	50.0%	1
My company doesn't participate in pilot projects		0.0%	0
My company does not file labeler codes, establishment registrations or drug listings		0.0%	0
Other, please provide details:	<div></div>	50.0%	1
	answered question		2
	skipped question		4

37. Have you already participated in the FDA eDRL Pilot Program?				
		Response Average	Response Total	Response Count
Number of Labeler Code Request SPL submissions		0.00	0	0
Number of Establishment Registration SPL submissions		0.00	0	0
Number of Product Listing/Content of Labeling SPL submissions		0.00	0	0
	answered question			0
	skipped question			6

38. If you are not familiar with the FDA’s Electronic Submission Gateway (ESG), please skip to the Company Organization section				
			Response Percent	Response Count
SKIP	<div><div></div></div>		20.0%	1
Continue	<div><div></div></div>		80.0%	4
	answered question			5
	skipped question			1

39. How do you plan to send your submission to the FDA?			
		Response Percent	Response Count
Use an existing ESG account(s)	<div><div></div></div>	50.0%	2
Create a dedicated ESG account(s) just for eList	<div><div></div></div>	50.0%	2
Use a third party		0.0%	0
No plans yet		0.0%	0
Other, please provide details:		0.0%	0
	answered question		4
	skipped question		2

40. Select the best description of the labeling and listing activities within your corporation/business group:			
		Response Percent	Response Count
Combined Regulatory Product Listing and Labeling group	<div><div></div></div>	60.0%	3
Separate Regulatory Product Listing and Labeling groups, The groups are in the same building		0.0%	0
Separate Regulatory Product Listing and Labeling groups, The groups are in separate buildings on the same site	<div><div></div></div>	20.0%	1
Separate Regulatory Product Listing and Labeling groups, The groups are on different sites		0.0%	0
Other, please provide details:	<div><div></div></div>	20.0%	1
	answered question		5
	skipped question		1

41. How do you expect your organization’s structure will change to effectively meet the FDA electronic submission requirement?			
		Response Percent	Response Count
No change	<div></div>	80.0%	4
Hire more people for current process		0.0%	0
Change lines of communication		0.0%	0
Reorganize department reporting structure		0.0%	0
No plans yet		0.0%	0
Other, please provide details:	<div></div>	20.0%	1
	answered question		5
	skipped question		1

42. How does your corporation/business unit currently prepare electronic SPL submissions?			
		Response Percent	Response Count
Use a commercial off-the-shelf or configured software tool	<div></div>	40.0%	2
Use a customized software tool/system provided by one or more outside vendors	<div></div>	20.0%	1
Use an outsourced service	<div></div>	40.0%	2
Use an internally created system		0.0%	0
Don't currently prepare electronic SPL submissions		0.0%	0
Other, please provide details:		0.0%	0
	answered question		5
	skipped question		1

43. How do you expect your corporation/business unit will prepare your future electronic SPL submissions?			
		Response Percent	Response Count
Make no change to our existing SPL solution	<div><div></div></div>	40.0%	2
Add new users/business units to an existing SPL solution (e.g. Human Health SPL system)		0.0%	0
Purchase a software tool		0.0%	0
Use an outsourced service		0.0%	0
Create/use an internal system		0.0%	0
No plans yet		0.0%	0
Other, please provide details:	<div></div>	60.0%	3
	answered question		5
	skipped question		1

44. Optional: Email address in case we need to contact you to clarify any answers. Your email address will not be used for any other purpose. Contact Email:		
		Response Count
		4
	answered question	4
	skipped question	2

45. How did you hear about this survey?		
		<div>Response Percent</div> <div>Response Count</div>
SPL Working Group WIKI	<div> <div></div> </div>	<div>80.0%</div> <div>4</div>
SPL Working Group or Subteam meeting	<div> <div></div> </div>	<div>80.0%</div> <div>4</div>
Colleague inside my organization		<div>0.0%</div> <div>0</div>
Colleague outside my organization		<div>0.0%</div> <div>0</div>
Educational/training session		<div>0.0%</div> <div>0</div>
Other, please provide details:		<div>0.0%</div> <div>0</div>
	answered question	
	skipped question	